IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

FRESENIUS MEDICAL CARE HOLDINGS, INC., et al.,

Plaintiffs,

v.

BAXTER INTERNATIONAL, INC., et al.,

Defendants.

No. C 03-1431 SBA

ORDER

[Docket No. 477]

This matter comes before the Court on Defendants Baxter International, Inc. and Baxter Healthcare Corporation's (collectively, "Defendants" or "Baxter") Motion to Bar the Expert Testimony of Jeff Riley. Having read and considered the arguments presented by the parties in the papers submitted to the Court, the Court finds this matter appropriate for resolution without a hearing. The Court hereby DENIES Baxter's Motion to Bar the Expert Testimony of Jeff Riley [Docket No. 477].

BACKGROUND

Plaintiffs and counter-defendants Fresenius USA, Inc. and Fresenius Medical Care Holdings, Inc. (collectively "Fresenius") initiated this patent suit on April 4, 2003 by filing a Complaint for Declaratory Judgment of Non-infringement and Invalidity against defendants and counter-plaintiffs Baxter International, Inc. and Baxter Healthcare Corporation (collectively "Baxter"). Fresenius cited five patents in its complaint: (1) U.S. Patent No. 5,247,434 ("'434 Patent"); (2) U.S. Patent No. 5,326,476 ("'476 Patent"); (3) U.S. Patent No. 6,284,131 B1 ("'131 Patent"); (4) U.S. Patent No. 5,486,286 ("'286 Patent"); and (5) U.S. Patent No. 5,744,027 ("'027 Patent") (collectively "patents-in-suit").

On May 14, 2003, Baxter answered and counterclaimed that Fresenius' 2008H and/or 2008K hemodialysis machines infringe four of the five patents. On October 20, 2003, Baxter amended its answer and counterclaims to assert infringement of the '286 Patent.

On December 22, 2005, the Court-ordered deadline for filing expert reports, Fresenius submitted the Opening Expert Witness Report of Jeff Riley. *See* Sitrick Decl. at Ex. A (Riley Expert Report). Jeff Riley graduated from Kent State University and began his formal training as a perfusionist in 1972 at Ohio State University. *Id.* He graduated from Ohio State University and was recognized as an outstanding student in the School of Allied Medical Professions in 1974. *Id.* During his career as a perfusionist, Mr. Riley has used and studied a variety of different heart and lung machines, including models from Sarns, Cobe, Baxter, Medtronic, CINCO, PemCo, and Jostra. *Id.* He is also currently writing a chapter on computerized cardiopulmonary bypass for Gravlee's next edition of his textbook on cardiopulmonary bypass. *Id.*

Mr. Riley teaches and directs the perfusion education program at the Circulation Technology Division in the School of Allied Medical Professions at the College of Medicine of Ohio State University. *Id.* Additionally, he holds an adjunct faculty position in the Midwestern University graduate perfusion education program in Glendale, Arizona. *Id.* Mr. Riley served on the faculty of Midwestern University prior to his employment at Ohio State University. He also currently serves as the Director of Continuing Medical Education for the American Society of Extra-Corporeal Technology and is a special section editor in the *Journal of Extra Corporeal Technology*. *Id.*

Mr. Riley's personal experience with hemodialysis includes: (1) coursework and laboratory study in hemodialysis as a perfusion student; (2) an eleven-week clinical rotation where he performed hemodialysis as a student; (3) performing simultaneous hemodialysis and/or hemofiltration with cardiopulmonary bypass during clinical practice on numerous occasions; (4) writing protocols for perfusionists to conduct hemodialysis during cardiopulmonary bypass; (5) co-authoring and helping to generate data for peer-reviewed articles on the topic of hemodialysis and cardiopulmonary bypass; and (6) teaching the principles of concurrent hemodialysis and cardiopulmonary bypass in Ohio State University's perfusion education program. *Id.*

In his report, Mr. Riley sets forth his background and qualifications, provides a background and

history of extracorporeal circulation, provides a tutorial on cardiopulmonary bypass and heart/lung machines, compares cardiopulmonary bypass and hemodialysis, and details the use of heart/lung machines to perform hemodialysis. *Id.* Mr. Riley does not specifically address the patents-in-suit or provide an expert opinion with regard to the validity of any of the patents-in-suit.

On March 2, 2006, Baxter deposed Mr. Riley. On March 7, 2006, Baxter filed the instant Motion to Bar the Expert Testimony of Jeff Riley ("Motion to Bar Expert Testimony"). Baxter's Motion to Bar Expert Testimony is premised on Federal Rules of Evidence 403 and 702 and Federal Rule of Civil Procedure 26(a)(2)(B).

LEGAL STANDARD

A. Federal Rule of Civil Procedure 26

Pursuant to Rule 26(a)(2), a party is required to "disclose to other parties the identity of any person who may be used at trial to present evidence under Rules 702, 703, or 705 of the Federal Rules of Evidence." Fed. R. Civ. P. 26(a)(2). Further, under Rule 26(a)(2)(B):

> [The] disclosure shall, with respect to a witness who is retained or specially employed to provide expert testimony in the case or whose duties as an employee of the party regularly involve giving expert testimony, be accompanied by a written report prepared and signed by the witness. The report shall contain a complete statement of all opinions to be expressed and the basis and reasons therefor; the data or other information considered by the witness in forming the opinions; any exhibits to be used as a summary of or support for the opinions; the qualifications of the witness, including a list of all publications authored by the witness within the preceding ten years; the compensation to be paid for the study and testimony; and a listing of any other cases in which the witness has testified as an expert at trial or by deposition within the preceding four years.

Fed. R. Civ. P. 26(a)(2)(B).

B. Federal Rule of Evidence 702

The admissibility of expert testimony is governed by the Federal Rule of Evidence, primarily Rule 702. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993). Pursuant to Rule 702:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

Under *Daubert*, the district court acts as a "gatekeeper," excluding "junk science" that does not meet the standards of reliability required under Rule 702. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997); *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1229-30 (9th Cir. 1998). The court accomplishes this goal through a preliminary determination that the proffered evidence is both relevant and reliable. *Daubert*, 509 U.S. at 589-95. Scientific evidence is deemed reliable if the principles and methodology used by the expert proffering it are grounded in the methods of science. *Daubert*, 509 U.S. at 592 ("The proponent need not prove that the expert's testimony is correct, but that the methodology used by the expert was proper."). The Supreme Court has provided five non-exclusive factors to consider when assessing whether the methodology upon which an expert rests his opinion is scientifically reliable. These factors are: (1) whether the expert's theory can be or has been tested; (2) whether the theory has been subject to peer review and publication; (3) the known or potential rate of error of a technique or theory when applied; (4) the existence and maintenance of standards and controls; and (5) the degree to which the technique or theory has been generally accepted in the scientific community. *Daubert*, 509 U.S. at 593-94. The test for determining reliability is flexible and can adapt to the particular circumstances underlying the testimony at issue. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150-51 (1999).

A trial court has broad latitude in determining whether an expert's testimony is reliable and also in deciding how to determine the testimony's reliability. *United States v. Hankey*, 203 F.3d 1160, 1167 (9th Cir.2000). However, the Court's inquiry must "focus[] solely on [the] principles and methodology, not on the conclusions that they generate." *United States v. Prime*, 431 F.3d 1147, 1153 (9th Cir. 2005). "Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded." *Children's Broad. Corp. v. Walt Disney Co.*, 357 F.3d 860, 865 (8th Cir.2004) (citations omitted).

C. Federal Rule of Evidence 403

Under Federal Rule of Evidence 403, relevant evidence may be excluded if "its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative

evidence." Fed. R. Evid. 403.

ANALYSIS

In its Motion to Bar Expert, Baxter argues that Mr. Riley's testimony must be excluded because: (1) Mr. Riley did not read the patents-in-suit, and therefore his testimony is neither relevant nor reliable under Federal Rule of Evidence 702; (2) Mr. Riley's testimony would unfairly prejudice the jury, and therefore should be barred under Federal Rule of Evidence 403; and (3) Mr. Riley's expert report does not disclose his opinions, in violation of Federal Rule of Civil Procedure 26.

A. Reliability and Admissibility Under Rule 702

Baxter's assertion that Mr. Riley's testimony must be excluded because he failed to read the patents-in-suit is without merit. Although Baxter argues that Mr. Riley's report directly opines on issues of validity and therefore "usurps the jury's role in assessing and making determinations regarding critical facts about Fresenius' anticipation and obviousness defenses," it is clear that Mr. Riley's report does not purport to reach the ultimate issues of invalidity in this case.

First, nowhere in Mr. Riley's report does he opine on whether or not "the Sarns 9000 meets each limitation of the asserted patent" as Baxter claims he does. Instead, the Report discusses the Sarns 9000 in very general terms. The report also does not directly opine on whether or not cardiopulmonary bypass "is the same field of the inventors' endeavor or reasonably pertinent to the problem with which the inventors were involved." Instead, the report gives a brief overview of the two fields and provides a historical background of their development as well as the overlap and similarities involved in the two fields. As Fresenius points out, the closest Mr. Riley comes to opining on an ultimate issue is the generalized statement that "[t]here is significant overlap in the basic operative principles of CPB and dialysis and heart lung machines and hemodialysis machines have components and operating principles that are identical or similar." Based on the fact that Mr. Riley has had over thirty years worth of experience with these particular technologies, it is beyond dispute that Mr. Riley is qualified to make a statement of this nature. The report also does not purport to identify specific time periods for Mr. Riley's comparison between cardiopulmonary bypass and hemodialysis procedures, but rather focuses on the relevant body of knowledge Mr. Riley has developed over his career as a perfusionist and educator. Although Baxter contends that this lack of specificity with regard to time is fatal to the

reliability of Mr. Riley's opinions, there is no need for the report to have such specificity unless Mr. Riley is providing an opinion on anticipation. Since he is not, Baxter's argument does not apply.

Further, Baxter's argument that Mr. Riley is attempting to "define" certain patent claims is not persuasive. Although Mr. Riley discusses general principles related to perfusion and hemodialysis procedures in his report, and uses and describes certain terms such as "hemodialysis," "hemodialysis machine," and "ultrafiltration," his report does not purport to define or redefine these terms as they relate to the specific patents-in-suit. Instead, the terms are discussed in a manner that gives the trier of fact a basic understanding of the general principles upon which the report is based. Moreover, the "definitions" used in Mr. Riley's report do not conflict with the Court's construction of the claims.

In sum, Fresenius has established that Mr. Riley's report is not intended to provide an opinion on patent validity but instead is intended to provide the jury with a more generalized overview of cardiopulmonary bypass and hemodialysis procedures. Fresenius has also established that Mr. Riley's testimony will be used to help the jury better understand the evidence that will be presented at trial, including the basic principles of cardiopulmonary bypass and hemodialysis, thereby allowing the jury to make its own inferences. Based on Fresenius' representations, the Court finds that Mr. Riley's testimony is admissible.[1]

Contrary to Baxter's assertion, the practice of allowing an expert to educate the jury without necessarily expressing an opinion on the specific facts of the case, or even reaching an opinion at all, is regularly upheld. *See, e.g., U.S. v. Rahm*, 993 F.2d 1405, 1411 (9th Cir. 1993) ("[N]ot every expert need express, nor even hold, an opinion with regard to the issues involved in a trial. . . . [T]he key concern is whether expert testimony will assist the trier of fact in drawing its own conclusion as to a 'fact in issue.'"); *see also Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000) ("When analyzing the relevance of proposed testimony, the district court must consider whether the testimony will assist the trier of fact with its analysis of any of the issues involved in the case. The expert need not have an opinion on the ultimate question to be resolved by the trier of fact in order to satisfy this requirement."); *Erickson v. Baxter Healthcare, Inc.*, 151 F. Supp. 2d 952, 968 (N.D. Ill. 2001) ("an expert may explain

[1]Also due to Fresenius' representations, the Court has not considered Mr. Riley's testimony as providing an opinion on validity.

principles without applying them or offering an opinion on the ultimate issue").

In fact, the Advisory Committee notes to Rule 702 specifically address the use of expert testimony for such purposes. *See* Fed. R. Evid. 702 Advisory Committee Notes to the 2000 Amendments ("[I]t might also be important in some cases for an expert to educate the factfinder about general principles, without ever attempting to apply those principles to the specific facts of the case. For example, experts might instruct the factfinder on the principles of thermodynamics, or bloodclotting . . . without ever knowing about or trying to tie their testimony into the facts of the case."). The standard that should be applied to determine the admissibility of such expert testimony is also set forth in the Advisory Committee notes:

> For this kind of generalized testimony, Rule 702 simply requires that: (1) the expert be qualified; (2) the testimony address a subject matter on which the factfinder can be assisted by an expert; (3) the testimony be reliable; and (4) the testimony "fit" the facts of the case.

Fed. R. Evid. 702 (advisory committee notes).

Each of the requirements for admissibility is met here. Specifically: (1) Baxter does not challenge the qualifications of Mr. Riley as a skilled perfusionist, scholar, and educator; (2) the subject matter of the litigation is beyond the general understanding of the average layperson, and therefore, a tutorial on the basic technologies involved will assist the factfinder in making its determinations; and (3) Mr. Riley's testimony "fits" the facts of the case because it provides background contextual information about cardiopulmonary bypass and its relation to hemodialysis as well as providing the jury with a tutorial on the use and functionality of the Sarns 9000 heart/lung machine – a device that Fresenius contends is prior art.

Additionally, and importantly, Mr. Riley's testimony is also reliable under the standard *Daubert* analysis. In *Daubert*, the Supreme Court articulated a set of non-exclusive factors to assist the trial court's determination of the reliability of expert testimony. *Daubert*, 509 U.S. at 593 ("Many factors will bear on the inquiry, and we do not presume to set out a definitive checklist or test."). The three factors that are relevant and applicable in this case favor the admissibility of Mr. Riley's testimony by

demonstrating its reliability.[2]

First, the assertions made by Mr. Riley can be or have been tested. In fact, counsel for Baxter deposed Mr. Riley on March 2, 2006 and therefore had the opportunity to test or challenge Mr. Riley's factual and contextual assertions regarding cardiopulmonary bypass procedures, his knowledge of hemodialysis procedures, and also his experience with the concurrent application of cardiopulmonary bypass procedures and hemodialysis under certain circumstances.

Second, as demonstrated by the directory of publications listed on Mr. Riley's curriculum vitae, Mr. Riley's knowledge of perfusion as well as his understanding of hemodialysis has been tested through the process of publication and peer review. Third, it appears that Mr. Riley's assertions have been generally accepted in the scientific community. Indeed, as demonstrated by Mr. Riley's report, the concurrent use of cardiopulmonary and hemodialysis procedures is a practice that has been documented and explained in published scholarly journals.

Accordingly, Fresenius has met its burden in establishing that Mr. Riley's testimony is relevant, reliable, and admissible.

B. Unfair Prejudice and Compliance with Federal Rule of Civil Procedure 26

Finally, the Court declines to exclude Mr. Riley's testimony based on Baxter's assertion that it is unduly prejudicial. "'Undue prejudice' within [the context of Rule 403] means an undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one." Fed. R. Evid. 403 Advisory Committee Notes to 1972 Proposed Rules. As the Advisory Committee notes to Rule 403 state, "[i]n reaching a decision whether to exclude on grounds of unfair prejudice, consideration should be given to the probable effectiveness or lack of effectiveness of a limiting instruction." *Id.* Here, neither party disputes that Mr. Riley has *not* read the patents-in-suit and is *not* providing expert testimony on obviousness or anticipation. To the extent that there is any danger that the jury might be mislead that Mr. Riley is nevertheless expressing an opinion on these matters, this can be addressed by effective cross-examination and appropriate jury instructions. *See Daubert*, 509 U.S. at 595 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the

[2]The other two factors, which relate to known or potential error rate and the maintenance of standards and controls, are not applicable under the facts of this case.

burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."). Further, Baxter has admitted that it intends to introduce its *own* expert, Dr. J. Dennis Bruner ("Bruner"), to address Mr. Riley's conclusions.[3] Thus, precluding Mr. Riley from testifying on the grounds that he would unfairly "confuse" or "mislead" the jury is unnecessary.

In fact, the heart of Baxter's concern appears to be Fresenius' reliance on Mr. Riley's testimony in support of its summary judgment motion and in opposition to Baxter's cross-motion. However, the Court has been clearly apprised of the fact that Mr. Riley has not read the patents-in-suit and is not purporting to express an opinion on patent validity. To the extent that Fresenius is relying on Mr. Riley's testimony to establish anticipation or obviousness, Baxter's arguments go to the weight of Fresenius' evidence and will be addressed in the context of the summary judgment motions, when relevant. Baxter has, not, however, provided the Court with a valid basis for excluding Mr. Riley's testimony in its entirety. As such, Baxter's Motion is DENIED.

CONCLUSION

IT IS HEREBY ORDERED THAT Baxter's Motion to Bar the Expert Testimony of Jeff Riley [Docket No. 477] is DENIED.

IT IS SO ORDERED.

Dated: 5/15/06

Saundra B Armstrong
SAUNDRA BROWN ARMSTRONG
United States District Judge

[3]Since Baxter concedes that Dr. Bruner has prepared a report fully addressing Mr. Riley's conclusions, Baxter's assertion that Fresenius has violated Federal Rule of Civil Procedure 26 because his report does not specifically state "what [his] opinions are" is totally disingenuous. In fact, Fresenius produced Riley's expert report by the Court-ordered deadline and the report conforms, in all respects, with the requirements of Rule 26. Baxter's argument that the report must be excluded because Riley has not used the phrases "my opinions" and "the opinions expressed in this report" borders on frivolous.